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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/484,577	01/18/00	GORDON L	07419-029001

020985
FISH & RICHARDSON, PC
4350 LA JOLLA VILLAGE DRIVE
SUITE 500
SAN DIEGO CA 92122

HM12/1222

EXAMINER	
ROARK, J	
ART UNIT	**PAPER NUMBER**
1644	7

DATE MAILED: 12/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/484,577	Applicant(s) GORDON ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Notice to Comply with Sequence Rules* .

DETAILED ACTION

Sequence Compliance

1. The communication filed 11/20/00 is not fully responsive to the Office communication mailed 7/26/00 for the reason(s) set forth below and on the attached Notice To Comply With The Sequence Rules. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The Sequence listing and computer readable form (CRF) provided included only a partial listing of the sequences disclosed in the specification as-filed. Please refer to MPEP 2400, especially 2422.03, which indicates:

> All sequence information, whether claimed or not, that meets the length thresholds in 37 CFR 1.821(a) is subject to the rules.

Therefore, the amino acid sequences disclosed on pages 32-61 of the specification as-filed require SEQ ID NOS and incorporation into the Sequence Listing.

Applicant is reminded to amend the specification (including the Brief Description of Drawings) and claims as appropriate to reflect compliance with the Sequence Rules.

Restriction Requirement

2. The following is noted:

The claims encompass unique nucleic acid sequences as they read on encoding distinct proteins, as indicated in the specification as-filed on page 80, line 14. Since each nucleic acid sequence, encoded protein, and antibody to each protein differs with respect to their structure, physiochemical properties, and mode of action; a person of ordinary skill in the art would not envision one in view of the other.

Therefore, the restriction has been set forth for each as a separate group, irrespective of the format of the claims.

Sequences that are shown to encode fragments of the same protein would be eligible for regrouping.

Please also note that similar groups have been condensed using the format "I-IV.....drawn to SEQ ID NOS:1, 3, 5, 7, *respectively*", wherein Group I comprises SEQ ID NO:1; Group II comprises SEQ ID NO:3; etc.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I-IV. Claims 1-4, 10-16, 28 and 29, drawn to an isolated or recombinant nucleic acid having percent identity to SEQ ID NO:1, 3, 5, 7, respectively; encoding a polypeptide as set forth in SEQ ID NO:2, 4, 6, 8, *respectively*; vectors, host cells, primers and kits thereof, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, 320.1, and 810.

V-XII. Claims 5-16, 28 and 29, drawn to an isolated or recombinant nucleic acid having percent identity to SEQ ID NO:9-16, respectively; vectors, host cells, primers and kits thereof, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, 320.1, and 810.

XIII-XVI. Claims 17-24 and 31-32, drawn to an isolated or recombinantly expressed polypeptide encoded by a nucleic acid which hybridizes to a nucleic acid comprising SEQ ID NO:1, 3, 5, 7; respectively, a polypeptide which has sequence identity to SEQ ID NO:2, 4, 6, 8, respectively; fragments and kits thereof, and heterologous proteins comprising said polypeptides; classified in Class 530, subclass 350 and Class 435, subclass 810.

XVII-XXII. Claims 17, 21, 22, 24 and 31, drawn to an isolated or recombinantly expressed polypeptide encoded by a nucleic acid which hybridizes to a nucleic acid comprising SEQ ID NO:9-14, respectively; fragments and kits thereof, and heterologous proteins comprising said polypeptides; classified in Class 530, subclass 350 and Class 435, subclass 810.

XXIII-XXXII. Claims 25-27, 30 and 42, drawn to an antibody that specifically binds a polypeptide encoded by SEQ ID NOS:1, 3, 5, 7, 9-14, respectively; hybridomas and kits comprising said antibodies; classified in Class 530, subclass 387.1; and Class 435, subclass 810.

XXXIV. Claims 33, drawn to an array of oligonucleotide probes, classified in Class 435, subclass 6.

XXXV-XLIII. Claim 34, drawn to a method of diagnosing or determining predisposition for GCA by providing *an antibody* to a polypeptide encoded by SEQ ID NOS: 1, 3, 5, 7, 9-14, respectively; classified in Class 435, subclass 7.1.

XLIV-LII. Claims 34 and 35, drawn to a method of diagnosing or determining predisposition for GCA by providing an nucleic acid or primer pair derived from SEQ ID NOS: 1, 3, 5, 7, 9-14, respectively; classified in Class 435, subclasses 6 and 91.2.

LIII-LXI. Claims 36-37, drawn to a method of diagnosing or determining predisposition for GCA by providing a polypeptide encoded by SEQ ID NOS: 1, 3, 5, 7, 9-14, respectively; classified in Class 435, subclass 7.92.

LXII. Claims 38-39, drawn to a method for isolating nucleic acid sequences associated with GCA, classified in Class 435, subclass 6

LXIII. Claims 40-41, drawn to a method of isolating lymphocytes involved in the pathogenesis of GCA, classified in Class 435, subclass 347.

4. Groups I-XXXIV are different products. Nucleic acids, polypeptides, antibodies to the polypeptides, and DNA arrays differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups (I-IV and XIII-XVI) and (V-X and XVII-XXII) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

6. Groups XXXV-LXIII are different methods. These methods differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

7. Groups (XXIII-XXXII and XXXV-XLIII), ([I-XII, XXXIV] and (XLIV-LII), (XIII-XXII and LIII-LXI), and (XIII-XXII and LXIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case:
The antibody of Groups XXIII-XXXII can be used for affinity purification, in addition to the methods of diagnosing recited.
The nucleic acids of Groups I-XII can be used to express protein and as probes to obtain full length genes, as well as for the method of diagnosing recited.
The polypeptides of Groups XIII-XXII can be used to immunize mice, in addition to the methods of diagnosing and lymphocyte isolation recited.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
December 15, 2000

PHILLIP GAMBEL

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
12/20/00

Notice to Comply	Application No. 09/484,577	Applicant(s) GORDON ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Please see Section 1 of the "Detailed Action"

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
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